Remarks/Arguments:

Newly presented claims 21-25 are pending.

Claims 21-25 correspond to original claims 11-15, respectively, amended to resolve the issues raised in the instant Office Action, as explained below.

Claims 1-20 are cancelled, without prejudice or disclaimer, with claims 1-10 and 16-20 being cancelled pursuant to restriction.

Present claims 21-25 are all limited to subject matter in connection with "Alzheimer's disease," i.e., reference to other neurodegenerative diseases (in the rejected claims) is not found in the present, newly added claims. The present claims do not contain the term "and/or," found in the cancelled claims.

Additionally, the present claims are limited to golgin-245 and a variant of golgin-245 encoding SEQ ID NOS: 2, 4, 6, or 8; i.e., reference to fragments and derivatives of golgin-245 have been deleted. The present specification provides a written description—in compliance with §112, ¶1—which enables in compliance with §112, ¶1—a skilled person to understand what is meant by variants—and to make and use— of golgin-245. The term "variants" is explained in detail in the instant specification, i.e., in the right column of page 3 of US 2006/0052280, starting at line 19 from the bottom. In line 6 variants of the golgin-245 protein are explicitly mentioned.

Use claim 12 is rewritten as method-of-use claim 22, which introduces necessary method steps.

The subject matter of elected claims 11-15 is allowable over the prior art, as implicitly found in the present Office Action, i.e., none of the elected claims was rejected under §102 or §103.

Claims 11-15 were rejected under 35 USC 101 as allegedly lacking utility. Claim 12 is rejected under 35 USC 112, second paragraph, for allegedly being a non-statutory "use" claim. Claims 13-15 were rejected under 35 USC 112, second paragraph, as allegedly being indefinite due to the claim terminology "disorders of one or more substances." Claims 12-15 were rejected under 35 USC 112, second paragraph, for being allegedly indefinite for reciting a narrow range or limitation within a broad range or limitation. Claims 11-15 were rejected under 35 USC 112, first paragraph, for allegedly failing to comply with the written description requirement. Claims 11-15 were rejected under 35 USC 112, first paragraph, for allegedly lacking enablement. Reconsideration is of the rejections is requested in view of the changes to the rejected claims effected by the instant amendment and the following remarks.

The rejection of claim 12 under §112, ¶2, is overcome in view of the subject matter of the rejected claim being rewritten, hereby, as (new) claim 22. Present claim 22 is a method-of-use claim, which expressly recites the method steps absent from the rejected claim. Accordingly, withdrawal of the rejection of claim 12 under §112, ¶2, appears to be in order.

The rejection of claims 13-15 under §112, ¶2, is overcome, since none of the present claims recites "disorders of one or more substances," the appearance of which in the rejected claims being the basis of the rejection. Accordingly, withdrawal of the rejection of claims 13-15 under §112, ¶2, appears to be in order.

The rejection of claims 12-15 under §112, ¶2 is overcome, since none of the present claims recites a narrow range or limitation within a broad range or limitation, appearance of which in the rejected claims being the basis of the rejection. Accordingly, withdrawal of the rejection under §112, ¶2, of claims 12-15 appears to be in order.

The rejections of claims 11-15 for allegedly lacking utility under §101, for allegedly failing to comply with the written description requirement under §112, ¶1, and for allegedly lacking enablement under §112, ¶1, apparently rely on essentially the same argument. Essentially, the PTO alleges that one of ordinary skill in the art would not have found credible the stated use of the presently claimed invention. Therefore, these rejections are addressed, together, in the following remarks.

As explained above, all of the present claims are limited to subject matter in connection with "Alzheimer's disease," i.e., reference to other neurodegenerative diseases (in the rejected claims) is not found in the present, newly added claims.

The statement of rejection acknowledges, with respect to the Alzheimer's-disease-related subject matter in the rejected claims—as opposed to the claimed subject matter relating to other neurodegenerative diseases—"it [the present specification] discloses the over-expression of the mRNA encoding for golgin-245 in brain samples taken from patients affected with Alzheimer's disease" and "The fact that Applicant found by differential display that golgin-245 is over-expressed in the brain[s] of patients with Alzheimer's disease," and further "Mutations of distinct genes such as presenilin and amyloid precursor proteins (Alzheimer's disease) . . . are the cause of distinct

neurodegenerative diseases with distinct clinical manifestations [citation omitted]" (Office Action, page 5). The statement of rejection also acknowledges (Office Action, paragraph bridging pages 5 and 6) "the art teaches that a defective axonal transport could be implicated in the pathogenesis of Alzheimer's disease." Nevertheless, the statement of rejection concludes (Office Action, page 7) "at the time the invention was made and even in the present, there was no function attributed to golgin-245 and the mere fact that golgin-245 is over-expressed in the brain[s] of patients with Alzheimer's disease, as identified by differential display, is not in itself a proof that golgin-245 is related to the pathology of Alzheimer's disease" (emphasis added). Applicants submit that, with all due respect, the conclusion reached with respect to Alzheimer's disease, the subject matter to which the present claims is limited, is incorrect.

In satisfying §101:

> The threshold of utility is not high: An invention is "useful" under section 101 if it is capable of providing some identifiable benefit. *See Brenner v. Manson*, 383 U.S. 519, 534 (1966); *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571 (Fed. Cir. 1992) ("To violate 101 the claimed device must be totally incapable of achieving a useful result"); *Fuller v. Berger*, 120 F. 274, 275 (7th Cir. 1903) (test for utility is whether invention "is incapable of serving any beneficial end").

Juicy Whip Inc.v. Orange Bang Inc., 51 USPQ2d 1700, 1702 (Fed. Cir. 1999). Total incapacity is necessary to demonstrate lack of enablement with respect to the invention claimed. *Tol-O-Matic Inc. v. Proma Produkt-Und Marketing Gesellschaft m.b.H.*, 20 USPQ2d 1332, 1338 (Fed. Cir. 1991).

> An invention need not be the best way or the only way to accomplish a certain result, and it need only be useful to some extent and in certain applications: "[T]he fact that an invention has only limited utility and is only operable in certain applications is not grounds for finding lack of utility" [*citation* omitted].

Carl Zeiss Stiftung v. Renishaw PLC, 20 USPQ2d 1094, 1100 (Fed. Cir. 1991).

As taught in the subject application (page 6, last ¶), applicants "detected" transcripts of the gene coding for golgin-245 in human brain samples and, additionally, found disregulation of golgin-245 transcripts in the brains—specifically, in the inferior temporal lobe or in the hippocampus—of patients having Alzheimer's disease; whereas, applicants found no such disregulation in the brains of age-matched patients not suffering from Alzheimer's disease. As explained in the first paragraph on page 7 of the subject application, the aforesaid "link"—between the disregulation of golgin-245 transcripts and Alzheimer's disease—provides "for the diagnosis and treatment of . . . AD [Alzheimer's disease]."

Accordingly, the subject application (paragraph bridging pages 12 and 13) the "causative role" of the golgin-245 gene and its transcription and translation products "in the regional selective neuronal degeneration typically observed in AD" or, alternatively, the "neuroprotective function" of golgin-245 with respect to the surviving nerve cells of AD patients. In any event, whether golgin-245 has the aforesaid "causative role" or, on the other hand, confers the aforesaid neuroprotective function, it satisfies the "threshold of utility," under §101—and, correspondingly, satisfies enablement-of-use, under §112, ¶1—since the PTO has failed to demonstrate that the presently claimed invention "is incapable of serving any beneficial end," *Juicy Whip Inc.*, 51 USPQ2d at 1702. Whether the presently claimed invention "has only limited utility" and may be "only operable in certain applications is not grounds for finding lack of utility." *Carl Zeiss Stiftung*, 20 USPQ2d at 1100. Since the subject application shows that a correlation exists between the disregulation golgin-

245 in the brain and the physiological effect of Alzheimer's disease, §101 utility is satisfied. *Hoffman v. Klaus*, 9 USPQ2d 1657 (BPA&I 1989).

The statements of rejection mistakenly rely on a number of cited prior art references. The reliance is misplaced because the cited references do not contradict the statement of utility for the presently claimed invention; the cited references merely point to alleged difficulties and need for further study/research in this area. Such teachings serve to demonstrate the patentability of the presently claimed invention, i.e., the cited references show that one of ordinary skill in the art would not have expected the presently claimed invention.

Since both of the rejections under §112, ¶1—for allegedly failing to satisfy the requirements for a written description and enablement of the presently claimed invention—are based on essentially the same reasoning as the §101 rejection for alleged lack of utility, the former rejections fall with the §101 rejection, i.e., for the aforesaid reasons traversing the §101 rejection.

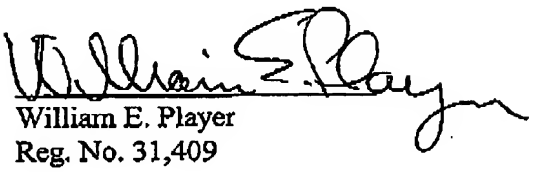
For the foregoing reasons, withdrawal of the rejections of the claims under §101, for allegedly lacking utility, §112, ¶1, for allegedly failing to satisfy the written description requirement, and §112, ¶1, for allegedly lacking enablement, appear to be in order.

Attorney Docket No. P67813US1
Application No. 10/511,096

Favorable action is requested.

Respectfully submitted,

JACOBSON HOLMAN PLLC

By 
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